syngenta

December 22, 2000

Pam Noyes
Special Review Branch
Special Review and Reregistration
Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Bldg.
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Dear Ms. Noyes:

Subject:	Comments on Preliminary Human Health Risk Assessment for Atrazine in Support of the Reregistration, Tolerance Reassessment, and Special Review

In response to the December 1, 2000 letter, Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.) is pleased to have an opportunity to provide our comments in the attached documents as part of the interim process used for FQPA tolerance reassessment. Following the instructions in the Agency's cover letter, Syngenta has focused on identifying and correcting errors in the various documents.

At the request of the Agency, we are providing a listing of additional ongoing research and/or documents on a variety of topics, along with projected dates of submission to the Agency. Also, as requested in the December 1 letter from EPA, Syngenta submitted a high-level summary of our comments via an electronic mail message on December 18. This summary, which has been revised, is also included in the comment document, along with background information and details on corrections. We are also including in the attachments to the comment document, additional information on agricultural practices and atrazine use, a presentation of time weighted data for the deterministic assessment, probabilistic assessments for diet and water, and a position paper on the Use of a 5% Factor Applied to the Application Rate for Assessment of Hand-to-Mouth Exposure to Turf Treated with Atrazine.

If the Agency makes substantial revisions to the preliminary draft of the RED using information that Syngenta has not had the opportunity to review we respectfully request an additional comment period that is adequate to address the changes. We also reserve the right to comment further on information referenced in the preliminary risk assessment documents but not made available to date.

As a result of our review of the various documents associated with the risk assessment, there are a number of policy and methodology issues that warrant further discussion.

Additional Information to Refine Risk Assessments

The Agency has indicated that additional data including probabilistic risk assessments is warranted to further refine the estimation of risk. Syngenta will cooperate in any manner possible to assist the Agency in developing the most refined and accurate risk assessments possible for atrazine prior to release for public comment. To allow for expedient review of the probabilistic risk assessments on diet and water included in our response we are providing a comprehensive report including a detailed description of methodology. We are also happy to provide an electronic copy of the database if requested. Further we will investigate the differences between analyses using the DEEM/Calendex models with analyses included in this response.

Toxicology

In the preliminary risk assessment conducted by the Agency, Syngenta disagrees with EPA's rationale on the following:

1. Retaining the 10X-uncertainty factor for extra sensitivity of infants and children.

2. Utilizing a chronic toxicity endpoint (LH surge suppression) to characterize short and intermediate term exposure.

3. Using a chronic toxicity endpoint developed for adults to characterize risks associated with exposure of infants and children.

4. Requiring a separate multi-generation reproduction study using Diaminochlorotriazine (DACT), when Syngenta has already performed or is performing more relevant comparative studies on more relevant endpoints.

Furthermore, the data indicate that there are significant differences in sensitivity to atrazine for even different strains of rats (e.g. Fischer-344 rat vs. Sprague-Dawley vs. Wistar). The Agency policy of using results from toxicity studies on the most sensitive strain and applying a 10X-uncertainty factor to allow for the possibility that man is more sensitive may not be appropriate. Syngenta intends to investigate this question experimentally by developing a physiologically based pharmacokinetic model for the SD rat and other species.

Syngenta also notes that the Agency has not established a policy to define acceptable risk in probabilistic risk assessments except for acute (single day) exposure. Syngenta has conducted several longer exposure duration probabilistic risk assessments on atrazine for large segments of the U.S. population and for a few selected community water systems and sub-populations whose size may range from a few individuals to a few thousand. Although from a policy viewpoint, the 99.9th percentile may be the appropriate "bright line" for acute toxicity evaluation in some situations, issues of the statistical reliability of the estimate remain. The 90th or the 95th percentiles are likely more appropriate for longer exposure duration. Syngenta will conduct a sensitivity analysis to determine the consequences of selecting different percentiles in a longer-term probabilistic risk assessment.

Occupational Residential Exposure

1. Mixer/loader/applicator scenarios have been included in the Agency's exposure assessment, which do not currently exist for atrazine.

2. Intermediate-term exposure risk assessments have been included in the preliminary RED that are inappropriate and should be removed.

3. The Agency has used assumptions for exposure determinations generated from draft Agency SOPs that have not yet been finalized.

4. The Agency questions the use of urinary total chlorotriazine residues for bio monitoring, when there is agreement that atrazine and its chlorotriazine metabolites are the moieties of toxicological concern.

5. The draft RED uses default assumptions in the risk assessment when actual exposure data are available.

6. The assessment is based, in part, on the highest average residue values, rather than measures of central tendency (mean values).

Residue/Dietary Exposure

1. The use of higher than supported label rates for corn, sugarcane, and other crops is not appropriate.

2. The assumptions of the percent of crop treated by atrazine for corn, sorghum, sugarcane, and other crops do not reflect current agricultural practices. Syngenta has provided substantial market research and usage information on atrazine for major crops for several recent years.

3. The proposed increase in the atrazine tolerance for milk is unwarranted.

Water Exposure

The weighting of monitoring data is important for accurate water exposure estimates of the total chlorotriazines. Also, higher tier probabilistic analyses provide the best methodology to assess risk through diet and water.

The Agency has noted in the draft preliminary RED a degree of uncertainty with respect to atrazine and metabolites in drinking water, relative to those areas deemed to be highly vulnerable to atrazine exposure in water. Syngenta has conducted extensive monitoring studies to characterize the potential for exposure to atrazine via surface water. In addition, we are conducting a synoptic study that will allow us to quantitate total chlorotriazine exposure in CWS ground water. When this project is complete, (March, 2001) Syngenta expects to be able to address the Agency's uncertainty issues.

The use of the rural well survey conducted by Syngenta in worst case settings of highly vulnerable aquifers and a history of atrazine detections as an indicator of rural wells in general is inappropriate. Syngenta has used the results of this monitoring as a vehicle for localized BMP/stewardship activities, which is consistent with the design of the survey.

Syngenta would also like to note our ongoing stewardship for improvement of water quality, which includes monitoring, research, education and development of best management practices. These stewardship efforts have resulted in implementation of Best Management Practices, which in part have resulted in the decline of levels of atrazine in selected agricultural watersheds.

If there are any questions concerning matters contained in this submission, please do not hesitate to contact either Janis McFarland at (336) 632-2354, or myself at (336) 632-7207.

Sincerely,

Thomas J. Parshley

Thomas J. Parshley
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Syngenta Crop Protection, Inc.

Enclosures